

Authority Paper

Committee:	Authority
Meeting Date:	9 th December 2009
Agenda Item:	4
Paper Number:	526
Paper Title:	Directors' Report
For information or decision?	Information

HFEA Directorates Report

Governance

Director's Report:

July – September (Q2)

Staff sickness continued to increase at a slightly higher rate in July, mainly as a result of continuing long term sickness cases as well as some self-certified sickness including three confirmed cases of swine flu in July and others with similar (but unconfirmed) symptoms. After this initial peak, sickness and absence rates have settled. Overall, this did not result in any significant impact on delivery of service, but is being monitored, particularly as we move into the autumn/winter.

More than half the organisation benefited from the Management training which was completed in mid-July. Formal Freedom of Information training was also delivered across the organisation for those taking on specific responsibilities in this area.

The 2009 pay remit was approved and pay awards were processed in the August payroll.

There has been a slight increase in staff turnover recently but recruitment is taking place. The position is being managed, particularly by the use of some short-term temporary contracts in support roles. However, there is pressure in some areas, notably in Committee Administration.

The HTA terminated the legal SLA with the HFEA with effect from 30 September 2009. As a consequence of the HTA bringing the legal services 'in-house', the affected staff member transferred to the HTA on that date under TUPE.

Preparatory work has been completed to enable the HFEA to move to a standard annual leave year starting 1 October.

Business Plan outcomes achieved by the end of Q2:

New licensing processes were successfully developed; ELP has been put in place with its first meeting on 14 October 2009; staff and Members trained in legal requirements, decision trees etc.

Appeals Committee appointments were made and introductory letters sent.

The organisational operating model and new Directorate structure is now embedded. To further improve governance arrangements, from 1 October 2009, Licence Committee Administration transferred to the Chief Executive's Directorate.

New policies, procedures and ways of working have been put in place to deliver implementation. Compliance team training days were held in September.

An all staff event to recognise the effort that staff had put into preparations for 1 October was well-received.

The successful preparation for and running of the Annual Conference (on 1 October, just after Q2) shows the increased effectiveness and confidence of the organisation.

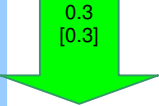
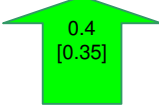
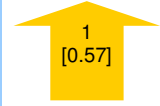

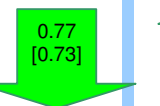


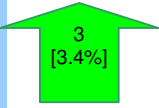

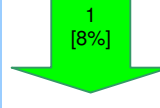
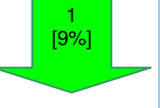
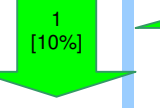
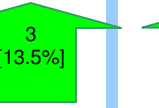
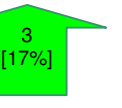


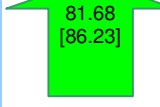
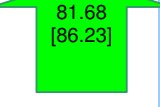
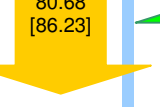
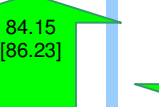

Oct –

Sickness rates have increased slightly overall, although one long term sickness absence has ceased as a consequence of a staff transfer. The other is being monitored.

The corporate annual leave year commenced on 1 October 2009. This was in conjunction with the launch of HR.net self service system for staff to use to book annual leave which will also make it easier for managers to access information about their staff.

There has been some staff turnover but this is being managed and recruitment is taking place. The recruitment process for the permanent Chief Executive started in October and interviews are taking place on 20 November.

ELP has now met several times and is intending to give all panellists, particularly non-Directors, opportunities to participate and the average time taken to consider each item of routine business before the ELP is working out at about ten minutes.

Work area	April	May	June	July	Aug	Sept	Oct
Staff absence: AWDL per staff month [year] (Civil Service average = 9 AWDL per staff year)	0.3 [0.3] 	0.4 [0.35] 	1 [0.57] 	1.2 [0.73] 	0.77 [0.73] 	0.81 [0.75] 	0.9 [0.77] 
Staff turnover: Actual per month [cumulative % rate of WTE for year]	3 [3.4%] 	3 [7%] 	1 [8%] 	1 [9%] 	1 [10%] 	3 [13.5%] 	3 [17%] 
Establishment (Actual WTE)	86.94 	78.98 [86.23] 	81.68 [86.23] 	81.68 [86.23] 	80.68 [86.23] 	84.15 [86.23] 	82.55 [86.94] 
Comments:							

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Compliance

Director's Report:

The inspection plan set out at the end of the previous business year has now been amended to reflect the clarification of inspection requirements relating to research licences, which, as for treatment licences, is biennially. The planned target for 2009/2010 has reduced from 148 to 89. Other changes are based on decisions of Persons Responsible not to renew their treatment or research licences.

Significant resources continue to be targeted at following up centres where improvements are needed, and managing complex litigation.

The new inspection tools are now being rolled out, with inevitable teething problems. We intend to review and refine them over the next 4 months so that they are finalised for the start of the next business year.

Business Plan outcomes achieved by the end of Q2:

New Directions and licence conditions established in keeping with new legislation.

New Directions published on website with new Code.

Review of research regulation process and documentation ready for implementation in October; HFEA prepared for newly licensable activities.

New process, guidance and documentation for embryos for training purposes.

New licences issued (new conditions).

New inspection processes in place. Improvements to the quality and consistency of inspections are in progress.

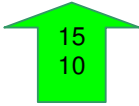




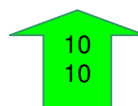
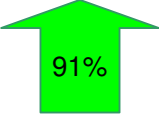
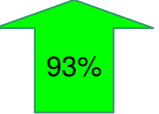
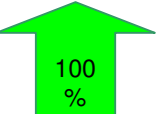
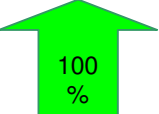
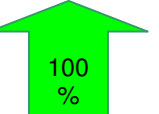

The risk tool is being developed (to be implemented for 2010/11 inspection plan).

Coherence of inspection with the new Code of Practice has been achieved.

The inspection programme for the year is on target for completion.

PREP has been revised and published (minimal electronic protected form version)

Compliance's QMS is being reviewed and improved – new tools, SOPs and methods are in the process of being developed.

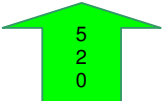

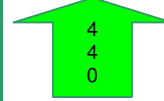
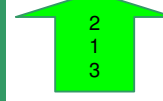
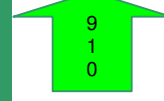

Work area	May	June	July	Aug	Sept	Oct
Inspections - Completed (month) - Planned (month)						
Reports resulting from initial application and renewal inspections of clinics and research establishments available to clinic within 28 working days of the inspection date (KPI 90%)						
New treatment and storage licence applications processed within 4 months of receipt of all necessary documentation and confirmation that the premises are ready for use (KPI 90%)	n/a	n/a	n/a	n/a	100% 1 x new application received	n/a
New research licence applications processed within 3 months of receipt of all necessary documentation and confirmation that the premises are ready for use (KPI 90%)	n/a	n/a	n/a	n/a	100% 2 applications received	n/a

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Work area	May	June	July	Aug	Sept	Oct
Import/export - applications received	0	2	1	1	3	2
Import/export - notifications received	31	60	46	24	39	n/a
Incidents reported	28	44	53	42	40	34
Incidents closed	63	36	54	40	43	0
Patient Complaints	2	2	3	8	2	1
Alerts	0	0	1	0	0	0
PGD - Applications received within 4 weeks (Exec) - KPI within 3 months (LC)						
PGS Applications received within 4 weeks (Exec) - KPI within 3 months (LC)	0	0	0	0	0	0
Comments:	Eight PGD applications for new conditions were received during October. One inspection report was late as equipment failure caused the loss of completed work.					

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Strategy and Information

Director's Report:

The period has again been dominated by the coming into force of the HFE Act 2008 on 1 October 2009, with work now focussed on responding to issues arising and finalising the work successfully done in the run-up. Highlights include:

Directions on Record Retention and Licence Applications published.

The publication of a leaflet for patients explaining the new consent to disclosure of information for research provisions.

Reviewing the online version of the 8th Code of Practice, which went live on 1 October, for teething and other issues.

Monitoring the new Choose a Fertility Clinic part of the website, which went live on 1 October, and trying to ensure all clinics are findable using 'search' facilities (with limited success for some clinics).

Review of the success of the Annual Conference and following up media and clinic interest on some of the issues raised.

Business Plan outcomes achieved by the end of Q2:

First draft of Hampton report received; discussions on the final report are ongoing.

The Authority has agreed in principle to seek RES Act powers in the future. More work is needed, post-implementation, on the new Compliance Cycle before deciding what powers are required and when the HFEA should apply for these.

Options for future presentation of information were developed, and the Authority agreed what clinic information and performance data should be published at its May meeting. The new Choose a Fertility Clinic part of the website went live on 1 October, and compares clinic data to national data in greater detail than ever before.

Long-term data analysis has been published (NPEU study on long term data (1992 - 2006/07) published April 09).

New consent forms have been issued and are being used to take consent going forwards from 1 October.

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The Opening the Register policy was in place ready for 1 October.

Quarterly updates are now published of outcome data and early pregnancy rates, through Choose a Fertility Clinic.

Information provision through website has improved. The website content and structure were redesigned and rewritten. User testing suggests that the new site is a real improvement on the old site.




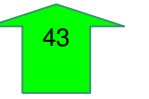



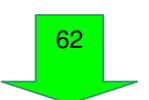
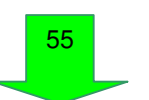

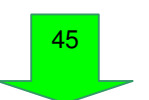


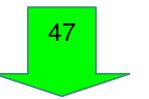
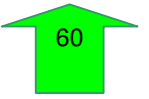
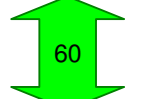
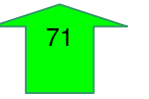
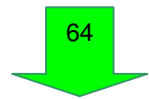


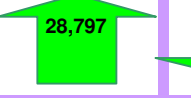

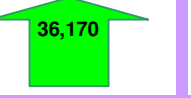

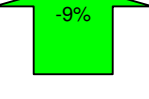
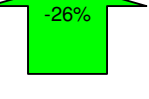
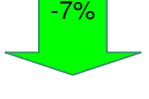
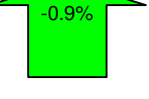








The new Code of Practice was published in July, and came into force on 1 October, with an online searchable version also published on 1 October.

Work to improve the understanding and awareness of new requirements in the sector is ongoing. There has been considerable dialogue with the sector including a series of regional seminars over the summer.

A programme of regular TRIM (document management system) training for staff has been established.

The planned policy process review has been embedded into forthcoming work on an organisation-wide QMS.

Progress on releasing Register data to researchers has been delayed pending Department of Health consultation on the regulations, including the fee to be raised. The scheme is now anticipated to come into force in May 2010.



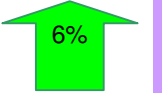

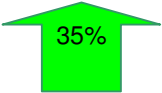
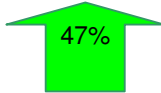



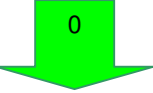
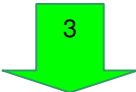

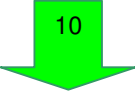









Work area	May	June	July	Aug	Sept	Oct
Number of public policy enquiries received	 45	 38	 42	 43	 68	 50
Number of public communications enquiries received	 83	 62	 55	 61	 45	 73
Number of media enquiries received by the Communications team	 63	 47	 60	 60	 71	 64
Number of website visits	 29,431	 23,426	 28,797	 26,328	 36,170	 42,944
Increase in visits to the HFEA website compared to 2008/09 (KPI 10%)	 -9%	 -26%	 -7%	 -0.9%	 6%	 10%
Number of 'find a clinic' visits	 8099	 7161	 9233	 8,377	 10097	 14352

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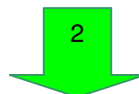

Increase in visits to the Choose a Fertility Clinic function on the HFEA website compared to 2008/09 (10%)						
Number of PQs					2	13
Respond to requests for contributions to Parliamentary Questions within deadlines set by the Department of Health (KPI 100%)	100%	100%	100%	N/A	100%	88% (1 missed)
Written enquiries from patients and the public responded to within 3 working days (PI = 95%)	738 (100%)	807 (100%)	705 (100%)	791 (100%)	745 (100%)	785 (100%)
Freedom of Information (FOI) and Environmental Information regulators (EIR) requests received						
Freedom of Information (FOI) and Environmental Information Regulations (EIR) requests dealt with within 20 working days						
% of Freedom of Information (FOI) and Environmental Information Regulation (EIR) requests closed	100%	100%	100%	100%	100%	100%

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within 20 working days (KPI)						
Data Protection Act requests dealt with within 40 working days (PI = 100%)	N/A	N/A	N/A	N/A	N/A	100% (1 request)
Opening the Register requests dealt with in 20 working days (excluding counselling time for the person making the request)						
% of clinics verified data published (quarterly return)	N/A	N/A	97.5%	N/A	N/A	97%
Number of Authority meetings held in public during the year (KPI 3)	N/A	N/A	Oxford	N/A	N/A	N/A
Comments:						

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Finance and Facilities

Director's Report:

Finance – Long-awaited work is now underway to develop improved income forecasting and so identify trends for the remainder of the financial year. Half year review meetings with all budget heads have been concluded and a list of additional spending items to be prioritised for 2009/10 has been prepared with some having budget implications for 2010/11. Business cases are in preparation for a number of important projects that DH has indicated a willingness to support in principle. Provision for additional areas of spend has been made within the CEO budget head pending final allocations of resources. DH has confirmed the withdrawn £460k grant-in-aid will not be restored due to a perceived 'lack of need' as demonstrated by excess fee income received and our closing month-end cash balances, and this has been factored into the revised income forecasts.

Facilities – Several small building works were completed relating to the office refurbishment. New and existing fire wardens were trained and a first meeting held. First Aiders received refresher training. The Business Continuity Plan is almost complete and is supporting us respond to swine flu developments. A review of the Vodafone account is currently underway with a view to cancelling numbers that are no longer required. A new, software based telephone system is under development to replace the existing Avaya system which has reached the end of its working life.

IT – This month, development has been largely focussed on the systems which provide the Risk Tool for use by compliance and preparatory work for the Voluntary Contact Sibling Register:

- The Risk Matrix creation tool.
- The online Self Assessment Questionnaire.
- The detailed statistical analysis of Register data to feed the tool.

Business Planning – Management of Licensing has transferred to the Chief Executive's office from 1 October. The Programme Management function has moved the other way to sit within Business Planning. CMG has agreed to the long-term ethos for this function and a permanent post has been established and recruited to (in November). The new Corporate Strategy and Business Plan for 2010/11 are now being progressed and items on these appear elsewhere on the agenda.

Business Plan outcomes achieved by the end of Q2:

The Clinic Portal now has four functioning online application forms for the import or export of gametes. Final adjustments are being made to the rule-based workflow management of the forms to route them to a decision and feedback the result to the applicant. A further range of forms is available for download and will remain paper-based until January 2010 whilst they are translated into an online version following an agreed plan for the remainder of 2009.

The HFEA is compliant with Cabinet Office rules on information governance and security. Recent mandatory online training has been reported internally and also to Audit & Governance Committee, whose members are also now progressing through the training. Despite all the other work required by 1 October, only a few HFEA staff have yet to complete (or in rare cases, start) their training.

Workflow systems will be able to be put in place for a range of different processes in the coming months. During the past quarter, IT staff ran some internal pilots on workflow leading to the first 'live' process supporting the online applications referred to above.

Summarised Management Accounts

£'000	Year to Date Results				Full Year	
	Actual	Budget	Variance	Forecast	Budget	Variance
OPERATIONAL ACTIVITY						
Income	341	3,712	-91	7393	7,225	168
REVENUE COSTS						
Chief Executive's Office	69	438	54	1,154	896	258
Staff Costs - Other	11	121	63	305	305	-
Authority / Committee Costs	21	128	77	311	381	-70
Compliance	120	713	77	1,512	1,595	-83
Strategy and Information	118	737	98	1,565	1,574	-9
Finance and Facilities	164	1,024	-4	2,109	2,055	54

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£'000	Sept-09	Year to Date Results			Forecast	Full Year	
	Actual	Actual	Budget	Variance		Budget	Variance
Legal Fees	40	-2	104	106	200	200	-
Professional Fees	5	18	14	-4	110	92	18
Total Revenue Costs	547	3,177	3,644	468	7,266	7,098	168
CAPITAL COSTS	9	83	56	-27	115	115	-
Total Costs	556	3,260	3,700	440	7,381	7,213	168
NET Operational Activities	-215	360	11	349	12	12	-
EUSTITE SUMMARY	- 0	-1	-6	-5	-12	-12	-
TOTAL NET ACTIVITY	-216	360	5	354	0	0	-

1 Key Issues

- 1.1 This report presents the September 2009 management accounts. Following a detailed review of these accounts with budget holders a number of revisions to forecasts have been made and these are noted in the following paragraphs. Where relevant, commentary has been added in respect of the October management accounts which are in the course of being finalised.
- 1.2 The accounts show a cumulative positive variance against budget of £360k, which has arisen primarily through material cost under-spends in most directorates. This cumulative and the September income outturn has been significantly affected by the withdrawal of £460k grant in aid by the Department. There has been a small increase (£28k) in October.
- 1.3 Work on improving fee forecasting continues. In the meantime, the forecast for monthly fee income has been increased by £680k. This will be utilised in part against the shortfall in grant in aid and also spend on additional projects in the remaining months of this financial year (subject to discussions with the Department where appropriate). However, additional funding for legal actions involving the Authority that are currently in progress may also be required.

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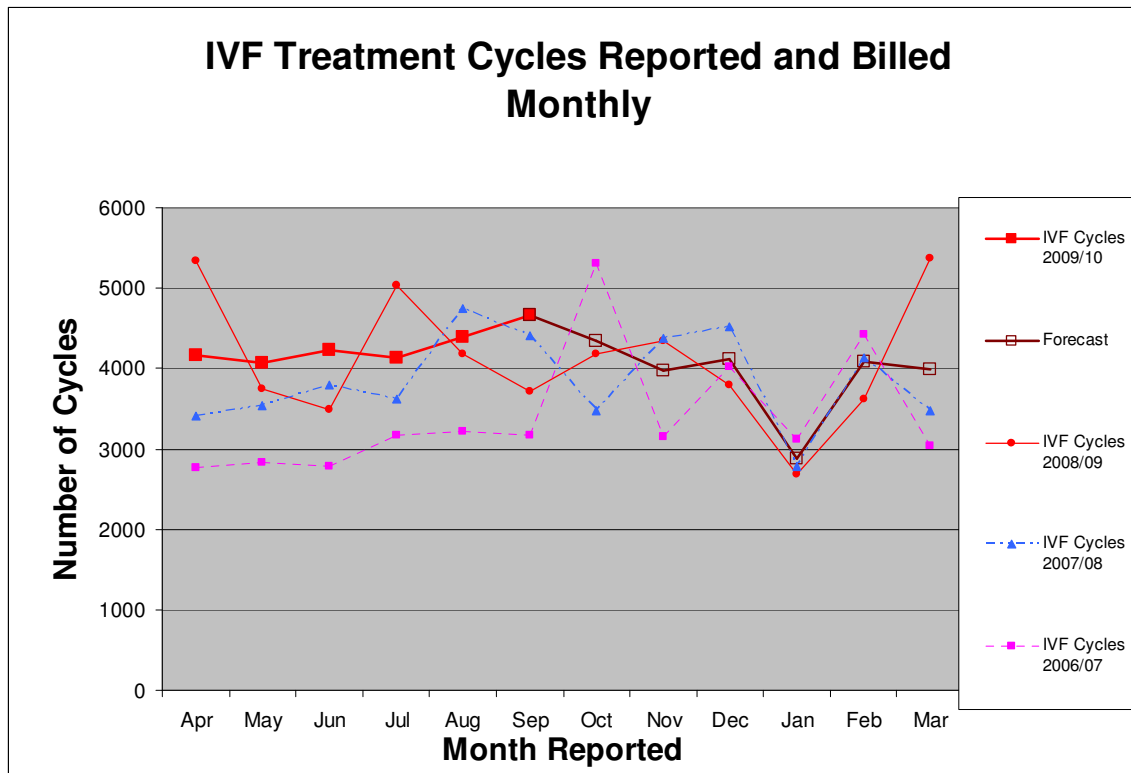
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2. INCOME

- 2.1 Cumulative fee income is £395k above budget. October and November fee incomes were substantially higher than budget also. Based on the outturn to date and preliminary results from the fee review currently underway, forecast monthly fee income has been increased by £680k for the year to £5.2m.
- 2.2 As anticipated, the forecasts for miscellaneous income and bank interest have been reduced by £37k in total, following the cessation of the last remaining SLA with the HTA, and the major fall in commercial bank interest rates.



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3 COSTS

3.1 Chief Executive's Office

- The underspend of £54k relates primarily to salaries which are lower due to changes in the team in the second quarter. The impact of these and forthcoming staff changes has been costed and the forecast for salaries decreased by £54k. £296k has been provided to meet the costs of a number of projects due for commencement and / or completion before the end of this financial year. Overall, after allowing for other forecast increases totalling £15k, the total net forecast increase within this budget head is £258k. There was no material variance in spend against budget in October.

3.2 Staff Costs – Other

- The net underspend of £63k in this budget head has increased materially from previous months. However, overall spend for the year is anticipated to be close to £305k. The cost outturn for October was above budget by £21k indicating that spend is accelerating. The forecast outturn for recruitment is anticipated to be significantly lower than budget. However, additional resourcing is required in respect of training (to include the Authority's contribution to the Talent Management Programme) and central maternity and long term sickness. Overall therefore the total forecast for the year is unchanged from the budget.

3.3 Authority / Committee Costs

- There are material cumulative underspends within this budget totalling £77k. Actual spend in October was almost equal to budget. Following a review of anticipated spend to the end of this financial year, the forecast has been decreased by £70k.

3.4 Compliance

- There are underspends against most costs in this directorate totalling £77k (net), the most material relating to salaries. Following a recalculation of staff costs to the end of this financial year, the forecast has been reduced by £85k. This is due to the impact of recent staff changes and long term sickness within the directorate. There are some other underspends, however spend is expected to accelerate significantly in the remaining months and this is supported by overspends in October.

3.5 Strategy and Information

- The underspend of £98k relates primarily to timing differences such as the costs of the annual conference which arose in October. Following the completion of the half year budget review a number of individual virements between cost heads have been calculated. The most material of these has been a forecast reduction of £44k in staff costs due to staff changes within the directorate, and recruitment now planned for later in the year. There has been an increase of £25k in respect of the annual conference, as it was agreed that additional resourcing should be provided for this. The net impact of these and other cost revisions is a net fall in total forecast spend of £9k. As anticipated, spend accelerated in October and the net underspend at the end of that month fell to £46k.

3.6 Finance and Facilities

- There is a net overspend of £4k. Following the half year review there have been a number of revisions to forecasts. There has been an increase of £78k in respect of service charges due to additional works undertaken by our landlords; a reduction of £42k in respect of forecast salaries costs; a reduction of £28k in building maintenance costs following the write back of an old accrual; and increases of £23k and £20k respectively for photocopying and internet costs. Overall, there has been a net increase in forecast spend of £55k. October costs were below budget by £18k leading to a cumulative underspend of £14k.

3.7 Legal Fees

- Whilst there is no overall change to the forecast, there are still a number of live litigation issues and a need for currently unquantified legal support in a number of areas. This budget therefore remains subject to a high level of uncertainty.

3.8 Professional Fees

- The 2009/10 internal audit programme has now commenced. The external audit programme is due to commence in January. Following agreement of the internal audit plan and assessment of the external audit costs relating to the forthcoming introduction of IFRS, the provisions for internal and external audit fees have been increased by £18k in total.

3.9 Capital Costs

- Capital costs are overspent to date due to the completion of the office refurbishment in the first quarter. Most of the remaining budget is to be spent on a new telephone system, currently under development. There is no change to the overall capital budget.

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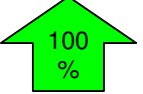


Work area	2008/09	May	June	July	Aug	Sept	October
Cash & Bank Balance – end of period (DH offer of new limit £750k)	1,147k 	936k 	1,001k 	1,449k 	985k 	894k 	641k
Invoices paid within 30 days –target 95%	92% 	97% 	97% 	98% 	95% 	96% 	99%
Debts collected within 60 days –target 85%	80% 	88% 	87% 	71% 	73% 	81% 	89%
Billing of clinics achieved within 3 weeks –target 95%	100% 	100% 	100% 	100% 	100% 	100% 	100%
Comments:	The month end cash balances have been falling primarily due to the Department's withdrawal of £460k grant in aid. The October month end balance was below the current DH offer of a new limit of £750k. Statistics for invoice payment and debt collection are improving significantly. Billing of clinics within 3 weeks remains consistent at 100%.						
EDI new records, of which % uncorrected by end month	No report run*	19,068 (8%)	20803 (2%)	18759 (4%)	19183 (4%)	22265 (5%)	19488 (7%)
EDI corrected records, of which % still with errors	No report run*	2,934 (17%)	2524 (3%)	2311 (12%)	2467 (6%)	3984 (8%)	1640 (8%)

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Work area	2008/09	May	June	July	Aug	Sept	October
EDI tickets from centres – raised / resolved	No report run*	12/23	22/23	14/8	29/20	36/32	34/36
Contacts to Reception: Weekly average, of which % by email	399 / 48%	389 / 47%	407 / 49%	361 / 49%	384 / 51 %	353 / 52 %	399 / 49%
Comments:	<p>EDI form volumes have returned to the levels prior to the verification exercise but, notably, the volume of forms with more than one correction has dropped substantially.</p> <p>Contacts to reception and the proportion of emails are remaining steady.</p>						
Number of items considered by Licence Committees	Not measured last year	27	21	25	11	23	3
Publication of finalised Licence Committee decisions on HFEA website within 20 working days of Chair sign-off (KPI 90%)	92.2%	 (23/23)	 (16/16)	 (23/23)	 (19/19)	 (28/28)	 (17/17)
Comments:	<p>In October, management of Licensing Committee services transferred to the Chief Executive's office. Notwithstanding the organisational and resourcing changes during the year, the website continues to be updated promptly.</p>						

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